

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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JAZZ PHARMACEUTICALS, INC. and  
JAZZ PHARMACEUTICALS IRELAND  
LIMITED,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.

Defendant.

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) Civil Action No. 2:15-cv-01360 (ES)(JAD)  
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**ROXANE LABORATORIES, INC.'S  
OPENING MARKMAN BRIEF  
IN SUPPORT OF ITS CLAIM CONSTRUCTIONS**

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Roxane Laboratories, Inc. respectfully submits this brief in support of the proper construction of certain claim terms of U.S. Patent Nos. 8,461,203 (“the ‘203 patent”), 8,772,306 (“the ‘306 patent”), 8,859,619 (“the ‘619 patent”), 8,952,062 (“the ‘062 patent”), and 9,050,302 (“the ‘302 patent”) (collectively, “patents-in-suit”), which are attached to the accompanying Declaration of Paul B. Sudentas in Support of Roxane Laboratories, Inc.’s Opening *Markman* Brief as Exhibits A-E,<sup>1</sup> respectively.

## **I. BACKGROUND**

The drug product at issue is sodium oxybate, also known as sodium gamma-hydroxybutyrate (NaGHB), which is a pharmaceutically active salt of gamma-hydroxybutyrate (“GHB”). GHB has been in medical use for over forty years for treating sleep- and pain-related conditions. (*See* Ex. A, ‘203 patent at 1:36-2:15.<sup>2</sup>) Sodium oxybate has potential for abuse as a euphoric and date-rape drug, so FDA and DEA regulate it as a controlled substance. In 2002, Orphan Medical, a predecessor company to Jazz Pharmaceuticals, Inc.,<sup>3</sup> received FDA approval to market sodium oxybate to treat narcolepsy under the brand name Xyrem®. Roxane filed an Abbreviated New Drug Application (“ANDA”) with FDA in 2010 seeking permission to market a generic sodium oxybate product.

Over the past six years, Jazz has filed nine complaints with this Court alleging infringement of the claims of 16 patents generally directed to GHB compositions, methods of treating sleep disorders using GHB, drug interactions between GHB and other medications, and

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<sup>1</sup> All exhibits referred to herein are attached to the Declaration of Paul B. Sudentas in Support of Roxane Laboratories, Inc.’s Opening *Markman* Brief.

<sup>2</sup> A citation to a patent in the form of “X:Y-Z” stands for column X, line numbers Y through Z.

<sup>3</sup> Plaintiffs in this action, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited are referred to, collectively, as “Jazz.”

restricted distribution systems for GHB. Presently before the Court in this action (C.A. No. 15-1360) are five of the most recently asserted of those 16 patents—the ‘203, ‘306, ‘619, ‘062, and ‘302 patents—from which Jazz is asserting 121 claims.<sup>4</sup> The five patents-in-suit can be broken into two families based on their earliest-filed common applications. The ‘203, ‘619, and ‘062 patents are part of the family of patents derived from U.S. Patent No. 6,472,431 (“the ‘431 patent”) (previously asserted by Jazz in related C.A. No. 10-6108), which are directed generally to sodium oxybate formulations, treatment methods, and packaging of such formulations. The ‘306 and ‘302 patents are members of a patent family that is new to the Court, and are generally directed to reducing the dosage amount of sodium oxybate when co-administered with another drug, divalproex sodium (also known as valproate and indicated for treating epilepsy) because of a drug-drug interaction. (We refer to the ‘306 and ‘302 patents as “the DDI patents”).

Of the 121 asserted claims in these five patents, the parties have narrowed the claim construction dispute to three claim terms—two in the ‘203 patent and one in the DDI patents. In addition, in its invalidity contentions regarding these patents, Roxane asserted that a few other claim terms are indefinite under 35 U.S.C. § 112. Although not presented here, Roxane does not waive any of those indefiniteness defenses, which the parties have agreed to address during expert discovery and trial.

## **II. ARGUMENT**

### **A. Legal Standards for Claim Construction**

The scope and meaning of patent claims are legal questions for the Court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The goal of claim construction is to

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<sup>4</sup> This Court previously issued a *Markman* opinion on September 14, 2012 in the related litigation. (*See* C.A. No. 10-6108, D.I. 151.) None of the claim terms presented in this brief were previously construed by the Court.

determine how a person of ordinary skill in the art would understand terms used in the patent claims at issue when the patent application was filed. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*). The proper meaning of claim terms is based first and foremost on the intrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Intrinsic evidence includes the claims, the patent specification, and the prosecution history. *See V-Formation, Inc. v. Benetton Group SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005). It also includes the art cited in a patent or during prosecution of the patent. *See, e.g., Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011). And, the prosecution histories of related patents are relevant to a claim construction analysis. *See, e.g., Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001) (“When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.”) (quoting *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999)); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1327 (Fed. Cir. 2007); *Masco Corp. v. United States*, 303 F.3d 1316, 1324 (Fed. Cir. 2002).

In construing claims, a court should first “look to the language of the claims to determine what ‘the applicant regards as his invention.’” *Phillips*, 415 F.3d at 1312. Terms that appear in more than one claim should be construed consistently throughout the patent. *Id.* at 1314. Moreover, claims and their terms are ordinarily interpreted consistently across patents having the same specification. *See In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1325 (Fed. Cir. 2011) *citing NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (“Because NTP’s patents all derive from the same patent application and share many common terms, we must interpret the claims consistently across all asserted patents.”).

A patent applicant “may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition is clearly stated in the patent specification or file history.” *Vitronics*, 90 F.3d at 1582. The specification is often regarded as “the single best guide to the meaning of a disputed term” due to its statutory role requiring written description and enablement of the claims. *See Phillips*, 415 F.3d at 1315-16. A claim term should not be construed so broadly that it does not find support in the specification. *See LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344 (Fed. Cir. 2005).

The prosecution history should also be considered, as it directly reflects how the patentee and the PTO understood the claimed invention, and informs the court on whether any claim interpretations were disclaimed during prosecution. *See Phillips*, 415 F.3d at 1317. The Federal Circuit has emphasized that the “‘undisputed public record’ of proceedings in the Patent and Trademark Office is of primary significance in understanding the claims.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996).

Extrinsic evidence may not be used to contradict the definition of a claim term derived from the otherwise unambiguous intrinsic evidence. *See Phillips*, 415 F.3d at 1324. “[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). A court may, however, look to extrinsic evidence to support a claim construction based on the intrinsic evidence, to understand the technology at issue, or to show that a term in the patent has a particular meaning in the relevant field. *See Phillips*, 415 F.3d at 1318; *Teva*, 135 S. Ct. at 841.



“The basic function of a patent specification is to disclose an invention. It has long been the case that a patentee ‘can lawfully claim only what he has invented and described, and if he claims more his patent is void.’” *Carnegie Mellon University v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (citing *O’Reilly v. Morse*, 56 U.S. 62, 121 (1853)).

## **B. The ‘203 Patent**

### **1. The person of ordinary skill in the art for the ‘203 patent**

Roxane proposes that the hypothetical person of ordinary skill in the art for the ‘203 patent (sometimes referred to as “POSA”), as of December 1998, would have an undergraduate or graduate degree in chemistry, pharmacy, or chemical engineering with 2-6 years of experience, depending on education level, and would have experience or familiarity with techniques for preparing pharmaceutically acceptable solutions that are chemically stable and resistant to microbial growth.

### **2. “admix”**

<b>Claim Term</b>	<b>Claim Phrase to be Construed</b>	<b>Roxane’s Proposed Construction</b>	<b>Jazz’s Proposed Construction</b>
“admix”	“ <i>admixing</i> a salt of gamma hydroxybutyrate with the aqueous medium” (Ex. A, ‘203 patent, claim 1)	“adding a salt of gamma-hydroxybutyrate to an aqueous medium, and then mixing the resulting medium”	No construction necessary
	“wherein the components are <i>admixed</i> sequentially” (Ex. A, ‘203 patent, claim 7)	“wherein a salt of gamma-hydroxybutyrate is first added to an aqueous medium and the resulting medium is then mixed”	

	“wherein the components are <i>admixed</i> simultaneously” (Ex. A, ‘203 patent, claim 8)	“wherein a salt of gamma-hydroxybutyrate is added to an aqueous medium, and the resulting aqueous medium is mixed at the same time”	
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Independent claim 1 and dependent claims 7 and 8 of the ‘203 patent recite the term “admix” in either the present tense (*i.e.*, “admixing”—claim 1) or past tense (*i.e.*, “admixed”—claims 7 and 8). Claim 1 refers to “admixing” with no modifier; while claims 7 and 8 modify how one should “admix”—indicating that the components are admixed “sequentially” (claim 7) or “simultaneously” (claim 8). Because the “admix” term is modified with different adjectives in claims 7 and 8 as compared to claim 1, Roxane has proposed constructions for each of the claim phrases where the claim term “admix” appears, in the context of claims 1, 7, and 8.

In a general sense, a POSA would have understood that the term “admix” refers to the process in which one component is added to another component followed by mixing the two components together. As discussed below, this comports with how this term is used in the claims of the ‘203 patent, where dependent claims 7 and 8 refer to the admixing of “the components” as “sequential” and “simultaneous.” Therefore, Roxane’s proposed constructions are squarely in line with a POSA’s understanding of “admix,” particularly in view of the claim language of claims 1, 7, and 8.

Although the ‘203 patent specification does not explicitly define the term “admix,” the specification is instructive of how a POSA would have understood the term. For example, the ‘203 patent refers adding sodium oxybate to an aqueous medium and then mixing the two items to dissolve the sodium oxybate, *e.g.*, “[c]omposition that are resistant to microbial growth are created by dissolving or mixing GHB in an aqueous medium...” (Ex. A, ‘203 patent at 3:42-45), “[t]he amount of GHB that may be mixed or dissolved into an aqueous medium...” (Ex. A, ‘203

patent at 3:51-53), “[w]hen the dosage unit form is a capsule for admixing with a specific volume of an aqueous medium...” (Ex. A, ‘203 patent at 15:44-47), and “[s]odium oxybate was dissolved in water” (Ex. A, ‘203 patent at 32:2 and 32:17). (*See also, e.g.*, Ex. A, ‘203 patent at 4:14-17, 4:29-32, 7:19-25, 8:49-56, 8:61-65, 12:55-63, 13:3-5, 14:53-59, 15:12-29, and 31:33-34; Ex. F, ‘431 patent file history, February 27, 2002 Interview Summary.)

The extrinsic evidence further supports Roxane’s proposed constructions, such as the American Heritage College Dictionary which defines “admix” not as just mixed, but as “mixed into” (Ex. G at ROXGHB054986). *See Phillips*, 415 F.3d at 1318 (explaining that “the court [Federal Circuit] has observed that dictionaries and treatises can be useful in claim construction”). Accordingly, “admix” necessarily requires that a component is added to another component and then mixed together. Moreover, as concerning claims 7 and 8, the ordinary meaning and extrinsic evidence also support Roxane’s proposed constructions. For example, the American Heritage College Dictionary defines “sequential” as “[f]orming or characterized by a sequence” (“sequence” is defined as “[a] following of one thing after another; succession”) and “simultaneously” as “happening, existing, or done at the same time.” (Ex. G at ROXGHB054988-89.) The concepts of “sequential” and “simultaneous” necessarily contemplate two steps occurring and here those steps are adding and mixing.

Further, claims 7 and 8, which depend from claim 1, recite “wherein the components are admixed sequentially” and “wherein the components are admixed simultaneously.” There is, however, no antecedent basis stating what is meant by “the components.” But because both claims 7 and 8 depend from claim 1 and because claim 1 recites that the claimed method “comprises admixing a salt of gamma hydroxybutyrate with the aqueous medium,” the POSA would understand that “the components” to be admixed in claims 7 and 8 are the salt of GHB

and the aqueous medium. Therefore, Roxane’s proposed constructions for claims 7 and 8 appropriately construe “the components” as a salt of GHB and an aqueous medium.

Furthermore, to the extent Jazz proposes that the plain meaning of “admix” is synonymous with “adding” as recited in claim 1 of the ‘431 patent (*see* Ex. H, ‘431 patent at 70:5-12), such a construction would run afoul of the doctrine of claim differentiation.

The doctrine of claim differentiation presumes that different terms in the same patent family have different meanings. *See, e.g., Unimed Pharmaceuticals, LLC v. Perrigo Company*, C.A. No. 13-326-RGA, 2015 WL 1094601, at \*8 (D. Del. Mar. 11, 2015) (applying the doctrine of claim differentiation to related patents in the same family); *Alstom Grid LLC v. Certified Measurement, LLC*, C.A. No. 15-72-LPS-CJB, 2016 WL 4151394, at \*7 (D. Del. Aug. 3, 2016) (explaining that “[t]he fact that different claims across related patents use these two *different* terms is meaningful in and of itself. ... This presumption, known as claim differentiation, may be applied between related patents.”) (emphasis in original). Here, Jazz chose to use two different terms in obtaining its patents—“adding” in the ‘431 patent and “admixing” in the ‘203 patent. Jazz should therefore be held to different meanings for the two different terms (“adding” being the broader term of adding with or without mixing, and “admixing” being the narrower connoting both adding and mixing). Indeed, during prosecution of the application that issued as the ‘203 patent, the applicants revised “*adding* gamma hydroxybutyrate” to recite “*admixing* a salt of gamma hydroxybutyrate.” (Ex. I, ‘203 patent file history, April 13, 2012 Amendment at 2 (emphasis added).) Obviously, the applicants’ replacement of “adding” with “admixing” indicates that the applicants were aware that “admixing” was not the same as “adding,” and intended to alter the meaning of the claim.

### 3. “contacting”

Claim Term	Roxane’s Proposed Construction	Jazz’s Proposed Construction
“contacting”	“to put or bring into physical contact or to physically touch two separate and distinct items”	No construction necessary
<p><b><i>Exemplary Claim Phrase(s) Containing the Claim Term to be Construed:</i></b></p> <ul style="list-style-type: none"> <li>• “<i>contacting</i> a salt of gamma hydroxybutyrate with the aqueous medium” (Ex. A, ‘203 patent, claim 10)</li> </ul>		

Claim 10 of the ‘203 patent requires the “contacting” of a salt of GHB with an aqueous medium. A POSA would have understood “contacting,” as recited in claim 10 and in view of the patent specification, to refer to the physical touching of one item with another item—*i.e.*, touching two separate and distinct objects. Thus, in the context of claim 10, a POSA would have understood “contacting” to mean putting or bringing into physical contact a salt of GHB with an aqueous medium.

While Jazz pretends not to understand how something can be separate and distinct in a solution, Jazz ignores the claim language and specification. It appears that Jazz believes that the claim requires that the salt of GHB already be in an aqueous medium, but such a reading of claim 10 includes limitations that are not present. Specifically, claim 10 requires “contacting a salt of gamma hydroxybutyrate with the aqueous medium,” which can occur only before the salt of GHB is in solution, *i.e.*, at the time the salt is first placed in contact with the aqueous medium. If the salt of GHB were already present in solution, there would be no need for the “contacting” step because the salt of GHB would already be in contact with the solution; therefore, such construction would improperly read the “contacting” step out of the claim. *See, e.g., Pause Tech LLC v. Tivo Inc.*, 419 F.3d 1326, 1334 (Fed. Cir. 2005) (in construing claims a court must “give

each claim term the respect it is due” such that every word within the term is afforded a separate meaning).

Further, the specification of the ‘203 patent illustrates examples of when the salt of GHB is brought into contact with an aqueous medium. For example, the ‘203 patent refers to the addition of sodium oxybate to an aqueous medium and then mixing the two items to dissolve the sodium oxybate, *e.g.*, “[c]omposition that are resistant to microbial growth are created by dissolving or mixing GHB in an aqueous medium...” (Ex. A, ‘203 patent at 3:42-45), “[t]he amount of GHB that may be mixed or dissolved into an aqueous medium...” (Ex. A, ‘203 patent at 3:51-53), “[w]hen the dosage unit form is a capsule for admixing with a specific volume of an aqueous medium...” (Ex. A, ‘203 patent at 15:44-47), and “[s]odium oxybate was dissolved in water” (Ex. A, ‘203 patent at 32:2 and 32:17). (*See also, e.g.*, Ex. A, ‘203 patent at 4:14-17, 4:29-32, 7:19-25, 8:49-56, 8:61-65, 12:55-63, 13:3-5, 14:53-59, 15:12-29, and 31:33-34; Ex. F, ‘431 patent file history, February 27, 2002 Interview Summary.)

Roxane’s construction is further supported by the extrinsic evidence and ordinary meaning. For example, the American Heritage College Dictionary defines “contact” as: “A coming together or touching, as of objects or surfaces;” “The state or condition of touching or immediate proximity” (Ex. G at ROXGHB054987). *See Phillips*, 415 F.3d at 1318 (explaining that “the court [Federal Circuit] has observed that dictionaries and treatises can be useful in claim construction”). Indeed, “a coming together or touching” of objects requires that there exist at least two objects, separate from one another, which are brought together.

### **C. The DDI Patents**

The DDI patents each claim priority to U.S. Provisional Patent Application Nos. 61/771,557 and 61/777,873 and have the same specification. Roxane will cite only to the ‘306 patent (Ex. B), unless expressly noted otherwise.

**1. The person of ordinary skill in the art for the DDI patents**

Roxane proposes that the POSA for the DDI patents, as of March 2013, would have at least a Ph.D., Doctor of Pharmacy degree, or medical degree, and five years of experience treating patients with neurologic disorders, including at least cataplexy or excessive daytime sleepiness in narcolepsy and/or five years of experience regarding drug metabolism, pharmacokinetics, and/or pharmacodynamics; a POSA may also include a clinical pharmacologist with at least three years of experience consulting with physicians on the dosing of drugs in light of potential drug-drug interactions, comorbid conditions, or other factors that could affect dosing.

**2. “concomitant”**

<b>Claim Term</b>	<b>Roxane’s Proposed Construction</b>	<b>Jazz’s Proposed Construction</b>
“concomitant”	“administration of a drug product to a single patient either subsequently, simultaneously, or consequently within two weeks of administration of a second drug product”	“the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administrated drug are still operative in the patient.”

***Exemplary Claim Phrase(s) Containing the Claim Term to be Construed:***

- “receiving a *concomitant* administration of valproate”  
(Ex. B, ‘306 patent, claim 1)
- “without *concomitant* administration of valproate”  
(Ex. B, ‘306 patent, claims 3, 8 and 11)
- “determining if the patient has taken, or will take, a *concomitant* dose of valproate”  
(Ex. B, ‘306 patent, claim 11)
- “administering to the patient a dose of divalproex sodium *concomitant* to a dose of GHB or a salt thereof”  
(Ex. E, ‘302 patent, claim 1)
- “in the absence of *concomitant* administration of divalproex sodium”  
(Ex. E, ‘302 patent, claims 1, 3, 5-8, 11, 13 and 19)
- “during *concomitant* administration of divalproex sodium”  
(Ex. E, ‘302 patent, claim 8)

The term “concomitant” should be construed consistent with the scope of the claims and the patentee’s own definition, both of which require that when sodium oxybate is administered with valproate, the administration of valproate occurs within two weeks of the sodium oxybate.

In the specification of the DDI patents, the patentee expressly defined “concomitant”:

“Concomitant” and “concomitantly” as used herein refer to the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient. *Thus, if the first drug is, e.g., Xyrem<sup>®</sup>, or GHB, and the second drug is valproate, the concomitant administration of the second drug occurs within two weeks, preferably within one week or even three days, before or after the administration of the first drug.*

(Ex. B, ‘306 patent at 8:37-45 (emphasis added).) The two drugs recited in the claims of the ‘302 and ‘306 patents are sodium oxybate and valproate (in the ‘302 patent claims) or divalproex sodium (in the ‘306 patent claims) (valproate and divalproex sodium refer to the same drug (*see, e.g.,* Ex. B, ‘306 patent at 15:19-35)); therefore, the language emphasized above is the patentee’s own definition as it applies to these claims. Roxane’s proposed construction recognizes that the



patentee chose to act as his own lexicographer for the term “concomitant” such that concomitant administration is administration of valproate occurring within two weeks of administration of sodium oxybate.<sup>5</sup>

Jazz’s proposed construction impermissibly broadens and adds vagueness to the meaning of “concomitant” by including only the first portion of the applicant’s definition of “concomitant” while ignoring the applicant’s explanation of what the term means when used in the specific context of the administration of sodium oxybate and valproate or divalproex sodium. *See, e.g., Pedicraft, Inc. v. Stryker Corp. of Michigan*, C.A. No. 02-334-J-16HTS, 2003 WL 25783586, at \*17 (M.D. Fla., May 5, 2003) (rejecting plaintiff’s proffered definition on the basis that allowing plaintiff to widen the scope of its claim term through such a broad and ambiguous definition would defeat the purpose of giving the public adequate notice of the limitations of the invention.); *Bayer Intellectual Property GmbH v. Warner Chilcott Company, LLC*, C.A. No. 12-1032-GMS, 2015 WL 1849015, at \*3 (D. Del. Apr. 21, 2015) (rejecting a proposed construction that conflicts with the intrinsic record and lacks defined boundaries because such construction “provides little guidance to one of skill in the art”); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350-51 (Fed. Cir. 2005) (*abrogated on other grounds by Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014)); *Interval Licensing LLC v. AOL, Inc. et al.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). Moreover, Jazz’s truncated construction adds ambiguity and subjectivity because a POSA would not know how to tell if “the effects of the first administered drug are still operative in the patient.” The DDI patents provide no test or method to assess what

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<sup>5</sup> The parties agreed during the meet and confer process that to the extent the Court later finds that the terms “also administering” and “currently taking” are not indefinite, the terms “also administering,” and “currently taking” that also appear in the DDI patent claims should have the same construction as the term “concomitant.”

“effects” are to be measured and how to determine if those “effects” are “still operative” in the patient after administration of the first drug.

Roxane’s proposed construction provides clarity and gives full credit to the patentee’s lexicography.

Dated: November 4, 2016

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